

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

2101-2150

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

OSCAR R. EWING, *Administrator, Federal Security Agency.*

WASHINGTON, D. C., December 22, 1947.

CONTENTS *

	Page		Page
Drug actionable because of potential danger when used according to directions.....	341	Drugs and devices actionable because of false and misleading claims.....	349
Drugs actionable because of failure to bear adequate directions or warning statements.....	342	Drugs for human use.....	349
Drugs actionable because of contamination with filth.....	343	Drugs for veterinary use.....	364
Drugs and devices actionable because of deviation from official or own standards.....	343	Drug actionable because of omission of, or unsatisfactory, ingredients statements.....	367
		Drugs actionable because of failure to bear accurate statements of the quantity of the contents.....	368

DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

2101. Adulteration and misbranding of dextrose injection and adulteration of epinephrine hydrochloride. U. S. v. Alpinol Corporation, Louis Rubella, and Ugo Quarantelli. Pleas of guilty. Fine of \$1,500 against the defendants, jointly. (F. D. C. No. 20153. Sample Nos. 4382-H, 5151-H.)

INFORMATION FILED: July 22, 1946, Southern District of New York, against The Alpinol Corporation, New York, N. Y., and Louis Rubella, president, and Ugo Quarantelli, secretary-treasurer, of the corporation.

ALLEGED SHIPMENT: Between the approximate dates of September 26 and October 2, 1945, from the State of New York into the State of Pennsylvania.

LABEL, IN PART: "Dextrose Injection * * * Distributed by Physicians' Drug & Supply Co., Phila., Pa." or "Epinephrine Hydrochloride 1:1000."

NATURE OF CHARGE: Adulteration, Section 501 (b), both products purported to be and were represented as drugs, the names of which are recognized in the United States Pharmacopoeia, but their quality and purity fell below the official standard in the following respects, and their variations from the standard were not stated on the labels: The *dextrose injection* was not sterile but was contaminated with viable bacteria, yeast, and mold, and it contained undissolved material. The *epinephrine hydrochloride* had a lower potency than the official product, and it contained undissolved material.

*For failure to comply with the packaging requirements of an official compendium, see No. 2115; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 2150; inconspicuousness, or absence, of required label information, Nos. 2115, 2135; cosmetics, subject to the drug provisions of the Act, Nos. 2121, 2150.

Misbranding, Section 502 (j) the *dextrose injection* was dangerous to health when used in the dosage prescribed, recommended, and suggested in the labeling, "Note: The contents are for use at one time * * * Directions: Administer slowly intravenously."

DISPOSITION: September 6, 1946. Pleas of guilty having been entered, the court imposed a fine of \$500 against the defendants, jointly, on each of the 3 counts of the information.

DRUGS ACTIONABLE-BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

2102. Misbranding of Pronto-Lax, Mineral Crystals, Famous Residuum, Nose Spraying Solution, and Eye Bath. U. S. v. Famous Mineral Water Co. and Howard Nevils. Pleas of guilty. Fine of \$100 against each defendant on count 1; fine of \$500 generally, but suspended for 3 years, against the defendants on the other counts of the information. (F. D. C. No. 20169. Sample Nos. 21861-H to 21865-H, incl.)

INFORMATION FILED: September 18, 1946, Northern District of Texas, against the Famous Mineral Water Co., a corporation, Mineral Wells, Tex., and Howard Nevils, secretary and treasurer of the corporation.

ALLEGED SHIPMENT: From the State of Texas into the State of Tennessee. The products were shipped on or about January 14 and April 3, 1945, and a number of circulars entitled "Dismuke's Famous Mineral Water" and "The Original and Genuine Famous Mineral Crystals" were shipped during December 1944.

PRODUCT: Analyses disclosed that the *Pronto-Lax* was an alkaline mineral water containing chiefly sodium sulfate (Glauber's salt) and sodium chloride (common table salt); that the *Mineral Crystals* was a partially crystallized sodium sulfate containing small amounts of sodium chloride and sodium carbonate; that the *Famous Residuum* was a concentrated mineral water containing mainly sodium chloride, sulfate, and carbonate, with some sodium nitrite; that the *Nose Spraying Solution* was a mineral water containing mainly sodium chloride, sulfate, and carbonate, with some sodium nitrate; and that the *Eye Bath* was essentially of the same composition as the *Nose Spraying Solution*.

LABEL, IN PART: "Dismuke's Pronto-Lax Concentrated Famous Mineral Well Water," "Dismuke's Famous Mineral Crystals," "Famous Residuum Made From The Crystals of the Famous Mineral Well Water," "Dismuke's Nose Spraying Solution," or "Dismuke's Eye Bath."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the respective products were false and misleading since the articles would not be effective to accomplish the purposes represented and suggested. The following false and misleading representations were made for the articles in the labeling:

That the *Pronto-Lax* was a tonic; that it would eliminate toxic poisons from the system, which poisons cause the majority of human ailments, and would eliminate poisons in a natural manner; that it would be beneficial to the stomach, kidneys, and liver; that it was life-saving, and would help suffering humanity; that it would make the user a "new man," and would keep the user in good health; and that it would improve digestion, and would be efficacious in the cure, mitigation, treatment, and prevention of diabetes, enlarged liver, carbuncle, mucous colitis, stomach trouble, ulcerated stomach, colon trouble, sciatica, rheumatism, hives, and autointoxication.

That the *Mineral Crystals* would be efficacious in the cure, mitigation, treatment, and prevention of acid stomach, colds, headaches, biliousness, indigestion, bad complexion, rheumatism, arthritis, neuritis, high blood pressure, and diabetes; that it would purify the system; that it would be beneficial after excessive eating and drinking; that it would enable the user to get well; and that it would eliminate toxic poison in the system.

That the *Famous Residuum* possessed tonic and healing properties, and would be efficacious in the cure, mitigation, treatment, and prevention of cuts, burns, insect bites, eczema, rash, poison ivy, acid stomach, acute indigestion, stomach trouble, ulcerated stomach, colic, and similar troubles; that it would enable the user to breathe normally and sleep soundly; and that it would tone up the digestive tract and prolong life,